UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

ALL ACTIONS

Master File No. 1:13-cv-09244 (RA) (SDA)

OPINION AND ORDER

STEWART D. AARON, United States Magistrate Judge:

Pending before the Court is Plaintiffs' Letter Motion seeking clarification of the scope of privilege waiver made by Defendants Takeda Pharmaceutical Co. Ltd., Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. (collectively, "Defendants" or "Takeda"), and seeking to compel Defendants to produce certain categories of documents withheld on privilege grounds. (Pls.' 8/30/22 Ltr. Mot., ECF Nos. 394 & 395.)[1] For the reasons set forth below, Plaintiffs' Letter Motion is GRANTED IN PART and DENIED IN PART.

BACKGROUND

This is an antitrust class action in which Plaintiffs allege that Takeda prevented competitors from timely marketing a generic version of Takeda's diabetes drug ACTOS by falsely describing two patents to the Food and Drug Administration ("FDA"). *See In re Actos End-Payor*

[1] ECF No. 394 was filed under seal and ECF No. 395 is a copy of ECF No. 394 with redactions. The Court shall issue a separate Order regarding the redactions in ECF No. 395.

Antitrust Litig., 848 F.3d 89, 92 (2d Cir. 2017). The relevant background for the privilege dispute before the Court is set forth below:[2]

I. The Hatch Waxman Act And The Listing Requirement

Under the Federal Food, Drug, and Cosmetic Act, brand-name drug manufacturers must obtain FDA approval to sell a new drug. 21 U.S.C. §§ 301-399. To do so, a manufacturer needs to file a New Drug Application ("NDA"), which includes among other information "a full list of the articles used as components of such drug" and "a full statement of the composition of such drug." 21 U.S.C. § 355(b)(1). If the new drug either is or contains a patented substance, the pharmaceutical company that owns the patent enjoys market exclusivity for the drug co-extensive with the patent's protection.

Meanwhile, the Hatch-Waxman Act simplifies the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy and costly NDAs. As a result, generic manufacturers need only file an Abbreviated New Drug Application ("ANDA"), which allows the applicant to rely on the FDA's previous safety and effectiveness findings for the brand drug they wish to replicate and bring to market. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv). Still, generics are prohibited from infringing the brand's patents; when a generic competitor submits an ANDA, it must provide a "certification" with respect to each unexpired patent related to the brand drug's

[2] Sections I and II below are excerpted from the Second Circuit's Opinion in *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd*., 11 F.4th 118, 124-28 (2d Cir. 2021). For the sake of brevity, while statutory and regulatory citations have been preserved, record citations and most case citations have been removed. In addition, quotation marks from language quoted by the Second Circuit in cases cited has been removed and the language quoted otherwise has been cleaned up. Finally, the Second Circuit's footnotes have been removed, and footnotes have been added to provide explanation and context, where needed.

production. The certification alerts the FDA to the relevant patent and explains why the proposed generic would not infringe it.

The Hatch-Waxman Act envisions two types of certifications, each providing a separate regulatory route for the production of a generic drug despite a brand pharmaceutical company's patent related to the drug. The first is commonly referred to as a "Paragraph IV" certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This certification states that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug." *Id*. The second is a "section viii" certification. 21 U.S.C. § 355(j)(2)(A)(viii). A section viii certification is appropriate where the generic company seeks only to market an unpatented method of using a substance in the public domain and certifies that it will "carve out" patented methods from its drug's production and labeled uses. *Id*.

Relevant to this case, Paragraph IV certifications activate powerful rights and restrictions on behalf of the patent-holding company. As an initial matter, it triggers a highly artificial act of infringement, permitting the brand manufacturer to sue the ANDA applicant. If the brand chooses to sue, the FDA is automatically prevented from approving the ANDA for the earlier of thirty months or the outcome of the litigation. The wait may be worth it, however, because the statute awards a 180-day period of market exclusivity to the first generic Paragraph IV ANDA applicant who is either not sued or who proves the patent invalid or not infringed by the generic. The exclusivity period begins to run "after the date of the first commercial marketing of the drug" by that generic applicant. 21 U.S.C. § 355(j)(5)(B)(iv). This imposed delay oftentimes creates a bottleneck effect of generic competitors who are ready and willing—but legally unable—to enter the market.

The consequences of filing a section viii certification, on the other hand, are much less dramatic. The process entails neither a 30-month litigation stay nor a 180-day exclusivity period. Thus, a generic manufacturer that files a section viii certification can more easily enter the market without delay.

Whether the generic manufacturer files a Paragraph IV certification or a section viii certification depends on how the brand drug manufacturer identifies the object patent(s) to the FDA. During the period relevant to this case, the specific language that a brand looked to in making this decision was found in the Hatch-Waxman Act's so-called "Listing Requirement" of 21 U.S.C. § 355(b)(1). In relevant part, that section provided:

> The applicant shall file with the application the patent number and the expiration date of any patent *which claims the drug* for which the applicant submitted the application or *which claims a method of using such drug* and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Id. (emphases added by Second Circuit). Related to the statutory Listing Requirement, an FDA regulation provides:

> An applicant . . . must submit to its NDA the required information . . . for each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents.
>
> ...
>
> *For patents that claim a drug product*, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA.
>
> *For patents that claim a method of use*, the applicant must submit information only on those patents that claim indications or other

> conditions of use for which approval is sought or has been granted in the NDA. The applicant must separately identify each pending or approved method of use and related patent claim(s).

21 C.F.R. § 314.53(b)(1) (reformatted and emphases added by Second Circuit).

If the brand manufacturer lists the patent as claiming the drug itself, a generic manufacturer must make a Paragraph IV certification asserting that the patent is invalid, expired, or otherwise will not be infringed by the generic version. For if the patent at issue is valid and current (and actually claims the drug), there is no way to produce a bioequivalent generic without infringing the patent. But if the brand manufacturer lists the patent as claiming a method of using the drug, the section viii certification affords the generic manufacturer an avenue to immediately produce its proposed drug provided only that the generic does so in a manner different from the patented method.

Because the FDA lacks both the expertise and the authority to review patent claims, rendering its own role with respect to patent listing ministerial, it does not independently assess the patent's scope or otherwise look behind the description authored by the brand. The use of improper designations during this process therefore throws a wrench into the FDA's ability to approve generic drugs.

II. Factual Background

In 1999, the FDA approved Takeda's Type-2 Diabetes drug ACTOS, a treatment tablet containing only one active ingredient—pioglitazone. In its NDA for ACTOS, Takeda listed U.S. Patent 4,687,777 (the "'777 Patent"), which consisted of pioglitazone and its pharmacologically acceptable salts, as claiming the drug ACTOS. The '777 Patent was set to expire on January 17,

2011, and, in 2007, the Federal Circuit upheld the patent's validity, thus definitively preventing generic entry into the pioglitazone market until after that expiration date.

Takeda twice supplemented its NDA—in 1999 and 2002—with information about newly-acquired patents: U.S. Patents 5,965,584 (the "'584 Patent") and 6,329,404 (the "'404 Patent"), respectively. Both patents, each set to expire in 2016, cover unique compounds containing pioglitazone and another active ingredient that, together, yield novel synergies not offered by pioglitazone alone. Specifically, the '584 and '404 Patents are pharmaceutical compositions which comprise an insulin sensitivity enhancer [*i.e.*, pioglitazone] in combination with other antidiabetics which shows a potent depressive effect on diabetic hyperglycemia. Because they are amalgams of separately identifiable constituent parts, both '584 and '404 are properly called "combination patents."

In its supplements for the ACTOS NDA, Takeda told the FDA that these combination patents both *claim the drug* ACTOS in addition to claiming methods of using ACTOS. Under normal circumstances, this would have compelled generic drug makers seeking to compete in the ACTOS market to file Paragraph IV certifications because one would have to undermine the validity of the '584 and '404 patents for the FDA to grant the ANDA. Complicating matters in this case, however, when the FDA published Takeda's supplemental patent information in its Orange Book—the go-to source of brand patent information—it listed the '584 and '404 Patents only as method-of-use patents.[3] Presumably, then, there was no reason at that time for a generic ACTOS maker to believe that a Paragraph IV certification was required for FDA approval.

[3] When the FDA approves a drug manufacturer's NDA, the manufacturer may list certain patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book"). *See*

Nevertheless, in 2003, three generic manufacturers[4] seeking to introduce a bioequivalent pioglitazone drug filed ANDAs containing Paragraph IV certifications with respect to patents '584 and '404. These companies agreed to share "first filer" status for purposes of the exclusivity period in marketing a generic version of ACTOS. Although their motivations for making this unnecessary certification remain unconfirmed, the competitive advantage from being a first filer under Paragraph IV for a generic ACTOS drug certainly provided a valuable incentive for doing so. Takeda thereafter sued the three generics for patent infringement.[5] After a trial, the district court entered judgment for Takeda solely based on the '777 Patent's continuing validity and enforceability but did not address the validity or enforceability of the combination patents. *Takeda Chem. Indus., Ltd. v. Ranbaxy Labs., Ltd.*, No. 03-CV-08250 (DLC), 2006 WL 618424, at *1-2 (S.D.N.Y. Mar. 13, 2006).

Other generics, however, refused to make paragraph IV certifications to the purported drug product claims and instead addressed only the method-of-use claims using section viii statements. For example, Teva Pharmaceuticals filed a section viii certification in July 2004, hoping that doing so would permit it to manufacture a non-infringing generic ACTOS without regard to any 180-day exclusivity period. This would have allowed Teva to come to market

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In re Bystolic Antitrust Litig., No. 20-CV-10087 (LJL), 2022 WL 323945, at *2 (S.D.N.Y. Feb. 2, 2022). The listing of the '584 and '404 Patents only as method-of-use patents was the result of a "significant flaw" in the FDA's standard Orange Book procedure. *In re Actos End-Payor Antitrust Litigation*, 848 F.3d at 98. Until August 2003, the Orange Book "could reflect only one description (*i.e.*, drug substance, drug product, or method of use) per patent. If a brand indicated that a patent claimed both a method of using a drug and the drug product itself, the Orange Book would only list it as a method-of-use patent." *Id*. at 98-99.

[4] The three generic manufacturers were Mylan Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc. and Ranbaxy Laboratories, Inc. *See United Food & Com. Workers*, 11 F.4th at 128 n.9.

[5] From 2003 until 2011, Takeda prosecuted in this Court the lawsuit referenced by the Second Circuit and others against prospective generic manufacturers. (*See* Pls.' 8/30/22 Ltr. Mot. at 3.)

immediately upon the '777 patent's expiration, while the Paragraph IV certification filers would have to wait.

Yet another generic drug manufacturer, Sandoz, Inc., filed a "citizen petition" with the FDA, asserting that Takeda had improperly caused the FDA to list the '584 and '404 patents in the Orange Book as drug product patents for ACTOS.[6] It therefore asked that the FDA require all ANDA filers to make Paragraph IV certifications in order to level the playing field among generics. At the FDA's behest, Takeda responded to the petition by reaffirming that it correctly listed the two patents as claiming both ACTOS as well as specific methods of its use. In light of Takeda's response, the FDA granted Sandoz, Inc.'s citizen petition and ruled that it would not approve a generic ACTOS ANDA that did not contain a Paragraph IV certification.

Plaintiffs allege that, as a result of these events, robust generic competition for Actos was improperly delayed for almost two years past January 17, 2011, when the '777 Patent expired.

III. Background Leading Up To Privilege Dispute

In their operative pleading in Case No. 13-CV-09244, *i.e.*, the Fourth Amended Complaint, filed March 14, 2018, Plaintiffs allege, *inter ali*a, that Takeda knowingly submitted false and misleading patent information to the FDA describing the '584 Patent and '404 Patent as drug product patents that "claim[]" ACTOS, causing them to be listed in the Orange Book as claiming ACTOS. (United Food Fourth Am. Compl., ECF No. 255, ¶¶ 4-5, 65-66.) Plaintiffs further allege that Takeda later reaffirmed its descriptions to the FDA in a subsequent response to a citizen

[6] The Second Circuit noted that Sandoz's "accusation appear[ed] to be incorrect" and that "the FDA listed the '584 and '404 Patents *only* as claiming methods of using ACTOS despite Takeda identifying them as also claiming the ACTOS drug itself." *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th at 128 (emphasis in original).

petition filed by Sandoz. (*See id*. ¶ 72.) In its Answer to that pleading, filed on October 22, 2019, Takeda asserted as an affirmative defense that "Plaintiffs' claims are barred because [Takeda's] actions were taken in good faith."[7] (*See* Defs.' 10/22/19 Answer, ECF No. 279, at 26.)

In their operative pleading in Case No. 15-CV-03278, *i.e*., the Fourth Amended Complaint, filed November 20, 2019, Plaintiffs allege, *inter alia*, that, Takeda knowingly and falsely submitted patent information to the FDA describing the '584 Patent and '404 Patent as drug product patents that "claim[]" ACTOS, causing them to be listed in the Orange Book as claiming ACTOS. (*See* Meijer Fourth Am. Compl., 15-CV-03278 ECF No. 152, ¶¶ 176-77, 180-83.) Plaintiffs further allege that Takeda wrongfully maintained the Orange Book listings for ACTOS as including drug product claims in the '584 and '404 Patents, including in response to the citizen petition submitted to the FDA by Sandoz. (*See id*. ¶¶ 251-55.) In its Answer to that pleading, filed December 6, 2019, Takeda asserted as an affirmative defense that "Plaintiffs' claims are barred because Takeda's actions were taken in good faith." (Answer, 15-CV-03278 ECF No. 173, at 74.)

On August 25, 2021, in an Opinion affirming the decisions of Judge Abrams denying the motions to dismiss in both Case No. 13-CV-09244 and Case No. 15-CV-03278, the Second Circuit held that Takeda's patent characterizations were wrong and that the '584 and '404 Patents do not "claim the drug" ACTOS. *See United Food*, 11 F.4th at 136. Thereafter, on April 22, 2022, Takeda provided notice to Plaintiffs that it was electing to waive privilege over the following subject matter: "[t]he applicability of the pre-2003 regulations governing the submission of

[7] This Court previously has noted that "to the extent a defendant accused of anticompetitive conduct asserts that the conduct was based on a good faith interpretation of binding regulations, that is a defense to an antitrust claim." *In re Actos End-Payor Antitrust Litig*., 417 F. Supp. 3d 352, 371 (S.D.N.Y. 2019), *aff'd*, 11 F.4th 118 (2d Cir. 2021). The burden is on Takeda to demonstrate its good faith effort to comply with the regulations. *See id*. at 375.

patent information to FDA (21 C.F.R. § 314.53) for U.S. Patent Nos. 5,965,584 and 6,329,404 in connection with ACTOS, and Takeda's compliance with those pre-2003 regulations." (*See* Defs.' 4/22/22 Ltr., ECF No. 394-1.)[8]

In May 2022, Takeda produced the documents that Takeda believed fell within the scope of its waiver, which documents previously had been withheld on the basis of privilege. (*See* Defs.' 9/1/22 Ltr. at 1.) In addition, in May and August 2022, Takeda produced categorical and metadata privilege logs reflecting the documents that Takeda withheld on privilege grounds. (*See* Pls.' 8/30/22 Ltr. Mot. at 1; Defs.' 9/6/22 Opp., ECF No. 403; *see also* Defs.' Categorical Logs, ECF No. 394-2; Excerpts from Defs.' Metadata Log, ECF No. 394-3.)

On August 30, 2022, Plaintiffs' filed the instant Letter Motion in which they assert that they are entitled to production of all documents relating to "Takeda's 'state of mind' with respect to the challenged misconduct, including its actual motives or intent," and in particular, documents falling into certain categories from Takeda's categorical privilege log.[9] (*See* Pls.' 8/30/22 Ltr. Mot. at 1-3; Privilege Log Categories, ECF No. 394-5.) Takeda's position is that it already has produced documents "relevant to Takeda's defense that the challenged conduct—Takeda's decision to maintain its 'patent characterizations' . . . for the '584 and '404 patents listed in the FDA's Orange Book for Actos—was a good faith attempt to comply with the law because

[8] Although Takeda's April 22, 2022 letter was filed under seal by Plaintiffs, Takeda set forth the relevant content of its April 22 letter in a letter that it filed with the Court on September 1, 2022. (*See* Defs.' 9/1/22 Ltr., ECF No. 398.)

[9] The documents to which Plaintiffs assert they are entitled are described by them as documents relating to "Patent Analysis" (Category Nos. 3, 15, 16 and 29); "Sandoz Citizen Petition ('CP') & Takeda's 2009/2010 Listing Reaffirmations" (Category Nos. 29 and 35); "Patent Litigation" (Category Nos. 1, 2 and 4); "Settlement Strategy/Negotiations" (Category No. 5); and "Hogan Lovells Retention." (*See* Pls.' 8/30/22 Ltr. Mot. at 3.)

Takeda understood based on the advice of counsel that the pre-2003 listing regulations (21 C.F.R. § 314.53) applied to Takeda's listing decision for the '584 and '404 patents for Actos and Takeda complied with those regulations," and that the documents Plaintiffs now seek "relate to topics as to which Takeda has not waived the privilege and which Takeda does not intend to rely on for its defense." (Defs.' 9/1/22 Ltr. at 1-2.)

On September 6, 2022, Takeda filed its opposition to Plaintiffs' Letter Motion. (*See* Defs.' 9/6/22 Opp.) In its opposition, Takeda asserts that it "has produced all privileged documents containing information that reflects or concerns the legal advice it received relating to the subject matter of its waiver," which documents "arise in various contexts, including: (i) Takeda's 2009 and 2010 correspondence and submissions to FDA concerning Sandoz's Citizen Petition; (ii) Takeda's draft (never filed) opposition to Teva's March 2010 motion in the ANDA litigation for leave to add a counterclaim challenging Takeda's '584 and '404 Patent listings as anticompetitive; (iii) Takeda's May 2010 letter responding to Teva's challenge pursuant to 21 C.F.R. § 314.53(f) to Takeda's '584 and '404 patent listings; and (iv) Takeda's July 2010 letter to FDA explaining, in the context of voluntarily amending patent "use codes," that the '584 and '404 patents were initially listed in 1999 and 2002, respectively, and thus governed by the pre-2003 regulations. (*See id*. at 8.)

On September 8, 2022, Plaintiffs filed their reply. (*See* Pls' 9/8/22 Reply, ECF Nos. 405-06.)[10] The Court held a telephone conference on September 9, 2022, during which Plaintiffs' Letter Motion was addressed. (*See* 9/9/22 Tr., ECF No. 410.)

[10] ECF No. 405 was filed under seal and ECF No. 406 is a copy of ECF No. 405 with redactions.

LEGAL STANDARDS

I. Attorney-Client Privilege And Waiver

"Where, as here, subject matter jurisdiction is based on a federal question, privilege issues are governed by federal common law." *In re Copper Mkt. Antitrust Litig*., 200 F.R.D. 213, 217 (S.D.N.Y. 2001) (citation omitted); *see also* Fed. R. Evid. 501. "The attorney-client privilege is one of the 'oldest recognized privileges for confidential communications.'" *In re County of Erie*, 546 F.3d 222, 228 (2d Cir. 2008) (quoting *Swidler & Berlin v. United States*, 524 U.S. 399, 403 (1998)). "Its purpose is to 'encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and the administration of justice.'" *Id*.

"A party . . . can waive privilege by placing privileged communications 'at issue' in the litigation by, for example, asserting reliance on counsel as a defense to justify its actions." *In re Lifetrade Litig*., No. 17-CV-02987 (JPO) (KHP), 2022 WL 3644357, at *2 (S.D.N.Y. Aug. 24, 2022) (citation omitted). With respect to the scope of the waiver, voluntary disclosure by or on behalf of a party during judicial proceedings may waive the privilege as to the disclosed information, as well as all the otherwise privileged information relating to the same subject matter of the disclosed information. *See In re von Bulow*, 828 F.2d 94, 101-02 (2d Cir. 1987). Subject-matter waiver applies where considerations of fairness should allow the "attacking party to reach all privileged conversations regarding a particular subject once one privileged conversation on that topic has been disclosed," *id.* at 102-03, in order to avoid prejudice to the adversary party and "distortion of the judicial process" that may result from selective disclosure. *Id.* at 101; *see also Fort James Corp. v. Solo Cup Co*., 412 F.3d 1340, 1349-50 (Fed. Cir. 2005) ("There is no bright line

test for determining what constitutes the subject matter of a waiver, rather courts weigh the circumstances of the disclosure, the nature of the legal advice sought and the prejudice to the parties of permitting or prohibiting further disclosures."); *McGrath v. Nassau Cnty. Health Care Corp.*, 204 F.R.D. 240, 243 (E.D.N.Y. 2001) ("the scope of any waiver is defined by the context of the waiver and the prejudice to the other party that limiting the waiver would cause" (citing *In re Grand Jury Proceedings*, 219 F.3d 175, 183 (2d Cir. 2000)).

Rule 502 of the Federal Rules of Evidence provides:

> When the disclosure is made in a federal proceeding or to a federal office or agency and waives the attorney-client privilege or work-product protection, the waiver extends to an undisclosed communication or information in a federal or state proceeding only if: (1) the waiver is intentional; (2) the disclosed and undisclosed communications or information concern the same subject matter; and (3) they ought in fairness to be considered together.

Fed. R. Evid. 502(a)(1)-(3); *see also United States v. Treacy,* No. 08-CR-00366 (JSR), 2009 WL 812033, *3 (S.D.N.Y. Mar. 24, 2009) (Rule 502(a) allows finding of subject-matter waiver of attorney-client privilege "in order to prevent a selective and misleading presentation of evidence to the disadvantage of the adversary" (quoting Advisory Note to Fed. R. Evid. 502(a))). Rule 502(a) establishes that "a subject matter waiver (of either privilege or work product) is reserved for those unusual situations in which fairness requires a further disclosure of related, protected information, in order to prevent a selective and misleading presentation of evidence to the disadvantage of the adversary." Fed. R. Evid. 502(a), Advisory Committee Notes.

"'Whether fairness requires disclosure . . . [is] decided . . . on a case-by-case basis . . . depen[ding] on the specific context in which the privilege is asserted.'" *In re County of Erie,* 546 F.3d at 229 (citing and quoting *In re Grand Jury Proceedings,* 219 F.3d at 183).

II. Work Product Doctrine And Waiver

"Federal law governs the applicability of the work-product doctrine in all actions in federal court." *Wultz v. Bank of China Ltd*., 304 F.R.D. 384, 393 (S.D.N.Y. 2015) (citing *Allied Irish Banks, P.L.C. v. Bank of America, N.A*., 252 F.R.D. 163, 173 (S.D.N.Y. 2008)). Federal Rule of Civil Procedure 26(b)(3) codifies the doctrine in part, providing that "a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent)," unless "the party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means." Fed. R. Civ. P. 26(b)(3).[11]

Parties may waive any work product protection by putting the privileged information at issue. *In re Grand Jury Proceedings*, 219 F.3d at 191. "The scope of the work product privilege

[11] "The Second Circuit has interpreted the 'in anticipation of litigation' requirement broadly." *Nat'l Cong. for Puerto Rican Rts. v. City of New York*, 194 F.R.D. 105, 108 (S.D.N.Y. 2000). "In anticipation of litigation" means that "in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation." *United States v. Adlman*, 134 F.3d 1194, 1202 (2d Cir. 1998) (citation and emphasis omitted). A substantial need exists "where the information sought is essential to the party's defense, is crucial to the determination of whether the defendant could be held liable for the acts alleged, or carries great probative value on contested issues." *Gucci Am., Inc. v. Guess?, Inc*., 271 F.R.D. 58, 74-75 (S.D.N.Y. 2010) (internal quotation marks and citations omitted). If a document reflects mental processes of an attorney, even a showing of "substantial need" and "undue hardship" may not suffice to set aside the presumptive immunity of the material from disclosure. *See*, *e.g*., *Adlman*, 134 F.3d at 1197, 1204 (discussing opinion work product). "Opinion work product receives higher protection so that litigation strategy is not revealed, and a party seeking to discover it must show 'extraordinary justification.'" *Strougo v. BEA Assocs*., 199 F.R.D. 515, 521 (S.D.N.Y. 2001) (citation omitted).

waiver is determined by considering whether a party has made affirmative and selective use of privileged documents, as well as the underlying purposes for the work product doctrine." *McGrath*, 204 F.R.D. at 245. Federal Rule of Evidence 502 applies with respect to waiver of work product protection, just as it does with respect to waiver of the attorney-client privilege. *See* Fed. R. Evid. 502(a). Thus, as in the attorney-client context, fairness and prejudice concerns define the scope of any work product waiver. *In re Grand Jury Proceedings*, 219 F.3d at 192; *Chase Manhattan Bank v. Turner & Newall*, 964 F.2d 159, 163 (2d Cir. 1992) (recognizing fairness doctrine).

ANALYSIS

Takeda is asserting a regulatory compliance defense (also referred to as a regulatory justification defense). (*See* Takeda 9/6/22 Opp. at 6.) The defense has two elements: (1) Takeda objectively "had a reasonable basis in regulatory policy to conclude" that its actions were required by regulation, and (2) Takeda subjectively "in good faith concluded" that its actions were required by regulation. (*See id*. (citing *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co*., 708 F.2d 1081, 1138 (7th Cir. 1983)). The regulatory compliance defense is applicable if the defendant "actually made its decision at the time in good faith on that basis rather than solely on the basis of competitive considerations." *In re Actos End-Payor Antitrust Litig*., 417 F. Supp. 3d at 371 (quoting *Phonetele, Inc. v. American Telephone & Telegraph Co*., 664 F.2d 716, 737 (9th Cir. 1981), *modified*, Nos. 77-3877, 77-2936, 1982 WL 11277 (9th Cir. Mar. 15, 1982)).

Takeda's reliance on advice of counsel defense is part of its regulatory compliance defense. (*See* Takeda 1/3/20 Opp., ECF No. 310, at 1 ("Reliance on the advice of counsel is one among many defenses that Takeda may assert in these antitrust actions, including as part of a

'regulatory justification' defense that Takeda had a good faith basis to believe its conduct was legitimate under the governing law and regulations.").) Takeda has chosen to waive privilege with respect to the applicability of the pre-2003 regulations governing the submission of patent information to the FDA (21 C.F.R. § 314.53) for the '584 Patent and '404 Patent, and Takeda's compliance with those pre-2003 regulations. (*See* Defs.' 4/22/22 Ltr.) Thus, based upon its express waiver, Takeda must produce all documents which formed the basis for the legal advice regarding this subject matter, all documents considered by counsel in rendering that advice, and all reasonably contemporaneous documents reflecting discussions by counsel or others concerning that advice. *See In re Pioneer Hi-Bred Int'l, Inc.*, 238 F.3d 1370, 1374-75 (Fed. Cir. 2001). In addition, Takeda must produce all documents that would otherwise have been protected under the work product doctrine that reflect or concern the subject matter of its waiver. *See McGrath*, 204 F.R.D. at 246.[12] The question remains, however, as to whether Takeda may limit its waiver to its chosen scope or whether fairness requires a broader scope. *See United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991) ("the privilege may implicitly be waived when defendant asserts a claim that in fairness requires examination of protected communications").

Plaintiffs advocate that the scope of the waiver should extend to all documents relevant to whether Takeda reasonably and in good faith concluded that its actions were required by a regulatory mandate, which they contend is broader than the waiver made by Defendants.[13] (*See*

[12] During the September 9 telephone conference, Takeda acknowledged that its waiver extended to documents subject to work product protection. (*See* 9/9/2022 Tr. at 7-8.)

[13] Plaintiffs rely upon a line of cases regarding the regulatory compliance defense arising in the telecommunications industry. (*See* 9/9/22 Tr. at 23.) The Court agrees with Plaintiffs that these cases set

9/9/2022 Tr. at 23, 26-27, 34.) As Takeda acknowledges, in order to establish its regulatory compliance defense, Takeda must have subjectively "in good faith concluded" that its actions were required by regulation. (*See* Takeda 9/6/22 Opp. at 6 (citing *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1138 (7th Cir. 1983)). Moreover, Takeda must show that it "actually made its decision at the time in good faith on that basis rather than solely on the basis of competitive considerations." *See In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d at 371. However, Takeda argues that "the documents that Takeda continues to withhold as privileged do not relate to the same subject matter—the applicability of and compliance with the pre-2003 regulations—that Takeda's reliance on the advice of counsel for its regulatory compliance defense places at issue." (*See* Defs.' 9/6/22 Opp. at 11 (internal quotation marks omitted).)

Upon reflection, the Court finds that limiting the scope of the waiver to the applicability of the pre-2003 regulations and Takeda's compliance with those regulations potentially shields communications at the heart of whether Takeda acted in good faith, which Takeda has placed at issue in its regulatory compliance defense. Especially if narrowly construed, production of

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forth the contours of the defense. However, to the extent Plaintiffs rely upon this line of cases for the proposition that "the whole concept of what good faith is, is in opposition to anti-competitive intent" (9/9/2022 Tr. at 23), the Court finds that the patent context is more nuanced since the very nature of patents is that they are anticompetitive. *See In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 233 (D. Conn. 2015) ("patent law—anticompetitive by design— . . . seeks to encourage innovation by rewarding innovators with limited legal monopolies"). Nonetheless, for purposes of this motion, the Court need not determine what constitutes good faith. It is enough for the Court to conclude, as I do for the reasons set forth herein, that Takeda's state of mind in complying with the regulatory mandate is relevant to its defense and that fairness requires a broader waiver than that proffered by Takeda. Moreover, the Court is mindful that case law is of limited assistance in determining the scope of a waiver because of the fact-intensive nature of the issues presented. *See In re Keeper of Recs. (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 22-23 (1st Cir. 2003) ("case law does not offer much assistance as to how broadly [] implied waivers sweep"); *see also Leviton Mfg. Co. v. Greenberg Traurig LLP*, No. 09-CV-08083 (GBD) (THK), 2010 WL 4983183, at *3 (S.D.N.Y. Dec. 6, 2010), *objections overruled*, 2011 WL 2946380 (S.D.N.Y. July 14, 2011) ("determinations of fairness must be decided on a case-by-case basis, in the specific context in which the privilege has been asserted, rather than on the basis of generalizations").

privileged documents only relating to the applicability of certain regulations governing the submission of patent information to the FDA for the '584 Patent and '404 Patent, and Takeda's compliance with those regulations, could deprive Plaintiffs of attorney-client communications and work product, if any, that potentially could rebut Takeda's assertion that, at the time it submitted patent information for the '584 Patent and '404 Patent to the FDA for listing in the Orange Book, and later in reaffirming its submissions, Takeda in good faith concluded that its descriptions of the '584 Patent and '404 Patent as drug-product patents that claim ACTOS were required by the regulations. In these circumstances, the Court finds that Plaintiffs would be prejudiced if Takeda's waiver is limited to its current scope, which could allow Takeda to use its privilege as both a sword and a shield.

Accordingly, the Court finds that fairness considerations dictate that the scope of the waiver include any communications, as well as any documents reflecting communications, between Takeda and its counsel, relating to Takeda's decision to list the '584 Patent and '404 Patent as claiming ACTOS and subsequent decisions to reaffirm the listings for such patents. The Court therefore hereby orders Takeda to produce any such additional communications and documents (excluding draft complaints, discovery responses and settlement agreements in the Actos ANDA litigations).[14]

The Court finds, however, that the expanded scope of Takeda's privilege waiver does not mandate the production of all documents in Takeda's Category Nos. 1, 2, 3, 4, 5, 15, 16, 29 and 35, as Plaintiffs have sought. Rather, Takeda shall proceed on a document-by-document basis

[14] Plaintiffs are not seeking draft complaints, discovery responses or settlement agreements in the Actos ANDA litigations. (*See* Pl.'s 9/8/22 Reply at 14 n.27.)

and need only produce those documents that fall within the expanded scope. The Court now turns to the specific documents submitted for *in camera* review.

* * *

The Court previously directed that Takeda produce for *in camera* review two documents selected by Plaintiffs and two documents selected by Takeda from each of the categories of documents to which Plaintiffs asserted they are entitled, as well as certain unredacted versions of other documents filed with the Court. (*See* 8/31/22 Order, ECF No. 396.) Upon review, the Court finds that certain of these documents may fall within the expanded scope of the waiver. However, as set forth below, before requiring Takeda to produce such documents, the Court will give Takeda an opportunity to show cause why they do not fall within the expanded scope and, therefore, should not be produced.

Category No. 1

Category No. 1 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, in the Actos, ActoPlus Met, and ActoPlus Met XR ANDA Litigation related to litigation strategy, analysis of patent infringement issues, and drafting, editing, reviewing, and analyzing pleadings and briefs." (*See* Privilege Log Categories.) Based upon my review of the following documents, they are not within the expanded scope of the waiver: TAK-ACTOS_000523024, TAK-ACTOS_000523021, TAK-ACTOS_000523066-67 and TAK-ACTOS_000579426-27.

Category No. 2

Category No. 2 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, related to drafting, editing, reviewing, and analyzing

discovery requests and responses, deposition preparation, and litigation holds in the Actos and ActoPlus Met ANDA Litigations." (*See* Privilege Log Categories.) Based upon my review of the following documents, they are not within the expanded scope of the waiver: TAK-ACTOS_000523240, TAK-ACTOS_000523511, TAK-ACTOS_000523308-09 and TAK-ACTOS_000523709-10.

Category No. 3

Category No. 3 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, related to ANDAs for generic Actos and ActoPlus Met, Hatch-Waxman Paragraph IV certifications for generic Actos and ActoPlus Met, loss of exclusivity for Actos and ActoPlus Met, and potential launch dates for both generic products based on patent expiration." (*See* Privilege Log Categories.)[15] Based upon my review of the following documents, they are not within the expanded scope of the waiver: TAK-ACTOS_000523896, TAK-ACTOS_000524789 and TAK-ACTOS_000524802.

Category No. 4

Category No. 4 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, related to drafting, editing, reviewing, and analyzing witness declarations/affidavits in the Actos ANDA Litigation." (*See* Privilege Log Categories.) Based upon my review of the following documents, they are not within the expanded scope of the waiver: TAK-ACTOS_000524933, TAK-ACTOS_000524935, TAK-ACTOS_000524949-50 and TAK-ACTOS_000524951-52.

[15] One of the documents selected by Plaintiffs was TAK-ACTOS_000524308, but Takeda now has agreed that this document falls within the scope of its express privilege waiver. (*See* Defs.' 9/6/22 Opp., Document Index, ECF No. 403-2, footnote 1.)

Category No. 5

Category No. 5 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, related to mediation in and settlement of the Actos ANDA Litigation, including draft settlement agreements containing and reflecting attorney edits and legal advice." (*See* Privilege Log Categories.) Based upon my review of the following documents, they are not within the expanded scope of the waiver: TAK-ACTOS_000527114, TAK-ACTOS_000525124-25 and TAK-ACTOS_000525530-31. However, the Court finds that the following document is not privileged: TAK-ACTOS_000572620, TAK-ACTOS_000572636-69 (document containing three tabs – (1) an RBC Capital Markets industry analysis; (2) Teva press releases; and (3) articles and other publicly available materials). There is no waiver issue here. Rather, these documents are not privileged and should be produced.[16]

Category No. 15

Category No. 15 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, related to drafting, editing, reviewing, and analyzing Takeda's New Drug Application for ActoPlus Met and ActoPlus Met XR submitted to the FDA. This includes requests for legal advice and legal advice provided related to regulatory requirements

[16] During the September 9, 2022 telephone conference, Takeda argued that this document was protected by the work product doctrine since it contained a compilation of documents selected by counsel. (9/9/2022 Tr. at 18-19.) However, "[n]ot every selection and compilation of third-party documents by counsel transforms that material into attorney work product." *In re Grand Jury Subpoenas Dated Mar. 19, 2002 & Aug. 2, 2002*, 318 F.3d 379, 386, (2d Cir. 2003). "To fit within what [the Second Circuit has] repeatedly characterized as a 'narrow exception' to the general rule that third-party documents in the possession of an attorney do not merit work product protection . . . the party asserting the privilege must show 'a real, rather than speculative, concern' that counsel's thought processes 'in relation to pending or anticipated litigation' will be exposed through disclosure of the compiled documents." *Id*. (citations omitted). No such showing has been made here.

under certain provisions of the U.S. Food, Drug, and Cosmetic Act and other applicable federal statutes and regulations." (*See* Privilege Log Categories.) Based upon my review of the following documents, they are not within the expanded scope of the waiver: TAK-ACTOS_000530164-65, TAK-ACTOS_000512281, TAK-ACTOS_000528611 and TAK-ACTOS_000580534-36.

Category No. 16

Category No. 16 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, related to drafting, editing, reviewing, and analyzing Takeda's New Drug Application for Duetact[17] submitted to the FDA. This includes requests for legal advice and legal advice provided related to regulatory requirements under certain provisions of the U.S. Food, Drug, and Cosmetic Act and other applicable federal statutes and regulations." (*See* Privilege Log Categories.) Based upon my review of the following documents, they are not within the expanded scope of the waiver: TAK-ACTOS_000512328-34, TAK-ACTOS_000528700-01[18] and TAK-ACTOS_000528698-99.

Category No. 29

Category No. 29 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, related to patent expiration dates, patent term extensions, analyses of infringement and prior art, and patent declarations, certifications, and related submissions to FDA, related to Takeda's patents covering Actos and ActoPlu[s] Met." (*See*

[17] Duetact is the tradename for drug products sold by Takeda containing a combination of pioglitazone hydrochloride and glimepiride. (*See* Compl. in *Takeda Pharmaceutical Co. v. Sandoz, Inc.*, No. 10-CV-03571 (DLC), ECF No. 1, ¶ 7.)

[18] Due to the small number of documents in Privilege Log Category 16, Plaintiffs and Takeda both selected this document. (*See* Defs.' 9/6/22 Opp., Document Index, footnote 2.)

Privilege Log Categories.) Based upon my review of the following documents, they are not within the expanded scope of the waiver: TAK-ACTOS_000530045, TAK-ACTOS_000530056 and TAK-ACTOS_000530054. For document TAK-ACTOS_000529979, the first two pages are not within the scope of waiver. However, it appears that the third page may refer to the listing for the '584 Patent and fall within the expanded scope and, thus, Takeda shall show cause why an unredacted version of the third page of this document should not be produced.

Category No. 35

Category No. 35 is described as follows: "Documents containing and reflecting requests for legal advice, and legal advice provided, pertaining to FDA's decision or anticipated decision, including the timing of any such decision and whether it will be publicly available, on the Citizen Petition filed in 2009 by Sandoz related to applications for generic Actos." (*See* Privilege Log Categories.) Based upon my review, the following documents are not within the expanded scope of the waiver: TAK-ACTOS_000580671, TAK-ACTOS_000530821 and TAK-ACTOS_000530843. However, the redactions contained in the document TAK-ACTOS_000530839 may fall within the scope of the expanded waiver and Takeda shall show cause why it should not be produced.

Unredacted Versions Of Documents Filed At ECF Nos. 394-4 and 394-6

Based upon my review, TAK-ACTOS_000527122-27, TAK-ACTOS_000525943-46 and TAK-ACTOS_000530015 do not fall within the expanded scope of the waiver. However, the redactions contained in TAK-ACTOS_000529984-91, TAK-ACTOS_000529995-530001 and on the first page

of TAK-ACTOS_000530835-38 may fall within the expanded scope of the waiver and, thus, Takeda shall show cause why they should not be produced.

One of the documents filed at ECF No. 394-4 (at PDF pp. 15 and 16) is TAK-ACTOS_000527117-18. Takeda has notified Plaintiffs that this document was inadvertently produced and now is asserting privilege as to such document. (*See* Defs.' 9/6/22 Opp. at 11-12 n. 10.) The Court finds that this document, which relates to a settlement conference in the ANDA litigation, does not fall within the expanded scope of the waiver and that it is properly withheld. Another document, labeled TAK-ACTOS_000527129-32, is filed both at ECF 394-4 at PDF pp. 22 to 25 and ECF No. 394-6 at PDF pages 10 to 13. Much of the content of this document was redacted, but one page was not (*i.e*., TAK-ACTOS_000527130). Takeda has notified Plaintiffs that this page also was inadvertently produced and now is asserting privilege as to such document. (*See id*.) Like the previous document discussed, the Court finds that this page, which relates to a settlement conference in the ANDA litigation, does not fall within the expanded scope of the waiver and that it is properly withheld.

Plaintiffs also seek documents from Hogan Lovells, a law firm that Takeda retained to give advice on regulatory issues. (*See* Pls.' 8/30/22 Ltr. Mot. at 3 & n.19.) A rolling production of these documents has commenced. (Takeda 9/6/22 Opp. at 7 n.7.)) Plaintiffs are entitled to production of documents from Hogan Lovells to the extent they fall into the subject matter as to which Takeda waived privilege, as expanded by the Court.[19]

[19] Takeda shall disclose to Plaintiffs whether any of the Hogans Lovell documents contain opinions that were not communicated to Takeda. If they do, then the Court expects the parties to meet and confer as to whether such documents will be produced and, if they are unable to agree, they shall brief this issue in light of conflicting case law on the issue. *Compare In re Buspirone Antitrust Litig*., 208 F.R.D. 516, 524-25

Finally, because there may be additional documents within the scope of Takeda's express waiver that inadvertently may not have yet been produced (as appears may have happened with the document addressed in footnote 15, *supra*), Takeda shall conduct a careful review of each of the documents withheld in whole or in part on privilege grounds.

CONCLUSION

By reason of the foregoing, Plaintiffs' Letter Motion is GRANTED IN PART and DENIED IN PART. It is hereby ORDERED, as follows:

1. No later than September 30, 2022, Takeda shall show cause in a written submission to the Court[20] why unredacted versions of TAK-ACTOS_000530839, TAK-ACTOS_000529984-91, TAK-ACTOS_000529995-530001; the third page of TAK-ACTOS_000529979 and the first page of TAK-ACTOS_000530835-38 should not be produced as within the expanded scope of the waiver;
2. No later than September 30, 2022, Takeda shall produce TAK-ACTOS_000572620, TAK-ACTOS_000572636-69;
3. No later than October 7, 2022, Takeda shall produce to Plaintiffs any communications, as well as any documents reflecting communications, between Takeda and its counsel, to the extent such documents relate to Takeda's decision to list the '584

(S.D.N.Y. 2002) (requiring production of uncommunicated opinions), *with Staley v. Gilead Scis., Inc.*, No. 19-CV-02573 (EMC) (LB), 2022 WL 1836820, at *1 (N.D. Cal. June 3, 2022) (privilege waiver found not to extend to materials that were not communicated to client and did not reference communications with client); *In re Lantus Direct Purchaser Antitrust Litig.*, 578 F. Supp. 3d 211, 215 (D. Mass. 2021) ("internal documents that were not communicated to Sanofi and do not reflect communications with Sanofi are not probative of Sanofi's—as opposed to its counsel's—state of mind").

[20] Takeda may redact from its submission material that it contends is protected by privilege and then file an unredacted version of its submission under seal.

Patent and '404 Patent as claiming ACTOS and subsequent decisions to reaffirm the listings for such patents (excluding draft complaints, discovery responses and settlement agreements in the Actos ANDA litigations);

4. No later than October 7, 2022, Takeda shall re-review the documents and/or portions of documents withheld and produce to Plaintiffs any documents within the scope of its express waiver that inadvertently were withheld; and

5. No later than October 7, 2022, Takeda shall file to the ECF docket a sworn declaration from a defense attorney having supervisory responsibility over the privilege review that the above-required productions were made in accordance with the provisions of this Order.

SO ORDERED.

Dated: New York, New York
September 16, 2022

Stewart D. Aaron

STEWART D. AARON
United States Magistrate Judge